

## **REMARKS**

### **A. The Status of the Claims**

Claims 1-6, 8, 10, 11, 13, and 14 have been previously canceled without prejudice. Claims 7, 9, 12, and 15-38 are pending.

### **B. Priority**

The effective priority date of the present application is October 6, 1999, for the following reasons. The present application claims priority to a PCT application PCT/JP00/06987 (WO 01/24790) filed on October 6, 2000. The PCT application was based on the Japanese national patent application JP11/285,735 filed on October 6, 1999. The priority was claimed when the PCT application was originally filed. The priority is also reflected on the filing receipt issued October 23, 2002, a copy of which is attached for the Examiner's easy reference.

It is clear that the PCT application was filed within 1 year of the filing date of the Japanese patent application, followed by the timely entry into the U.S. national stage. It is submitted that all the requirements under the Patent Cooperation Treaty and the Paris Convention have been satisfied, thus entitling the present application to the earliest effective filing date of October 6, 1999.

### **C. Rejections Under 35 U.S.C. § 103(a)**

Claims 7, 9, 12, 15-17, 19-24, and 31-37 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Miyata et al. (*Kidney International*, vol. 55, pp. 389-399 (1999)), in view of Ruggiero-Lopez, et al. (*Biochem Pharmacol.*, vol. 58, pp. 1765-1773 (1999))(page 2 of the Office Action). In addition, claims 18, and 25-30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Miyata et al. and Ruggiero-Lopez, et al. and in view of U.S. patent No. 5,928,916 (Keogh) (page 8 of the

Office Action). Finally claims 34-36, and 38 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,952,356 (Ikeda et al.) and Ruggiero-Lopez et al. (page 12 of the Office Action). These rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, the following three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference(s) as proposed by the Examiner; (2) there must be a reasonable expectation of success and (3) the prior art reference(s) must teach or suggest all of the claim limitations. The Applicants respectfully submit that none of the criteria has been satisfied in this case because none of the cited references, either alone or in combination, disclose or suggest every limitation of the pending claims.

Specifically, each of claims 7, 9, 12, 15-17, 19-24, and 31-37 recites carriers (claims 7, 9, and 23) or dialysis solutions (claim 12) that comprise biguanide agents, or methods for removing carbonyl compounds (claims 15 and 34) utilizing biguanide agents. The references cited by the Examiner do not disclose such limitations. The Examiner correctly pointed out that Miyata et al. lack such teaching or suggestion (page 4, lines 14-16 of the Office Action). The Examiner proposed to use the disclosure of Ruggiero-Lopez et al. disclosing dimethylbiguanide to cure the deficiency of the combination of Miyata et al. However, Ruggiero-Lopez et al. is not available as the proper prior art reference.

It is well established that a 35 U.S.C. § 103 rejection must be based on a subsection of 35 U.S.C. § 102. See, MPEP § 2141.01. In other words, to qualify as a valid 35 U.S.C. § 103 reference, the reference must also qualify as prior art under a section of 35 U.S.C. § 102. See, Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987).

As discussed above, the present application has the effective priority date October 6, 1999. The reference date for Ruggiero-Lopez et al. is December 1, 1999, its

publication date or, alternatively, October 29, 1999, the date when the Ruggiero-Lopez et al. reference has first become available on-line. Please see attached a copy of a printout from the ScienceDirect web site showing the abstract of the Ruggiero-Lopez et al. reference and the relevant dates. Therefore, the present application pre-dates Ruggiero-Lopez et al., thus making Ruggiero-Lopez et al. unavailable as prior art against the present application.

Therefore, Ruggiero-Lopez et al. does not qualify as a valid 35 U.S.C. § 103 reference. In view of the foregoing, it is respectfully submitted that each of claims 7, 9, 12, 15, 23, and 34 is patentably distinguishable over the references cited by the Examiner. Claims 16, 17, 19-22, 24, 31-33, and 35-37 depend, directly or indirectly, on one of claims 7, 9, 12, 15, 23, or 34, and are allowable for at least the same reason.

With respect to the rejection of claims 18 and 25-30, according to the Examiner, a combination of three references (Miyata et al., Ruggiero-Lopez et al., and Keogh) is required to show obviousness. As discussed above, Ruggiero-Lopez et al. is not a valid prior art reference. A prima facie case of obviousness cannot be established using only Miyata et al. and Keogh, because, as pointed out by the Examiner (page 12, lines 11-13), Ruggiero-Lopez et al. provide the motivation for using biguanidines.

Similarly, with respect to the rejection of claims 34-36, and 38, according to the Examiner, a combination of Ikeda et al. and Ruggiero-Lopez et al. is required to show obviousness. As discussed above, Ruggiero-Lopez et al. is not a valid reference. A prima facie case of obviousness cannot be established solely over Ikeda et al.

In view of the foregoing, it is submitted that the 35 U.S.C. § 103(a) rejection does not apply. Reconsideration and withdrawal of the rejection are respectfully requested.

**D. Double Patenting Rejection**

Claims 32-38 have been provisionally rejected under the non-statutory, judicially created doctrine of obviousness-type double patenting over the claims 13, 14, 20-23, 28-31, 36-38, and 45 of the co-pending U.S. patent application USSN 11/093,950 (page 16 of the Office Action). While the Applicant respectfully traverses this rejection, it is believed that this issue has become moot in view of the terminal disclaimer which accompanies this response. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In re Application of:  
Toshio Miyata  
Application No.: 10/089,789  
Filed: August 19, 2002  
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PATENT  
Attorney Docket No.: SHIM1130

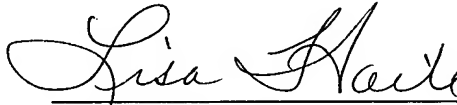
### CONCLUSION

In view of the above remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

A check in the amount of \$130.00 is believed due in connection with the filing of this paper. The Commissioner is hereby authorized to charge any additional amounts required by this filing, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

Date: November 3, 2005

  
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